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AMENDMENT AND RESPONSE TO OFFICE ACTION

## Amendment

## In the Claims

- 1. (currently amended) A composition dosage formulation for oral administration comprising an effective amount to treat a patient in need thereof of arsenic trioxide, wherein the composition is prepared by a method comprising: (a) adding arsenic trioxide to sterile water to form a first solution/suspensio; (b) adding sodium hydroxide to the first solution to form a second solution; and (c) adding hydrochloric acid to the second solution to form a third solution when administered orally, wherein the amount is less than the effective amount for intravenous administration.
- 2. (currently amended) The <del>composition</del> <u>dosage formulation</u> of claim 1, wherein the arsenic trioxide <del>in step (a)</del> is a powder.
- 3. (currently amended) The composition dosage formulation of claim 2, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.
- 4. (currently amended) The eomposition <u>dosage formulation</u> of claim 1, wherein the sodium hydroxide has a molar concentration of 3M <u>arsenic trioxide</u> is in a solution of sterile water adjusted to pH between 6 and 8.
- 5. (currently amended) The composition dosage formulation of claim 1, wherein the hydrochloric acid has a molar concentration of 6M further comprising at least one additional pharmacological agent.

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(currently amended) The composition dosage formulation of claim 5, wherein the Ó.

third-solution has a pH of 8.0 additional pharmacological agent is a chemotherapeutic.

7 (cancelled)

8. (cancelled)

9. (currently amended) The composition dosage formulation of claim 7.4, wherein

the final solution has an arsenic trioxide concentration of 1 mg/ml.

10. (currently amended) A composition for oral administration comprising arsenie

trioxide, whereinthe composition is prepared by a method comprising; (a) a first step of adding

500 mg of arsenic trioxide to 150 ml of sterile water to form a first solution: (b) a second step of

adding 3M sodium hydroxide to the first solution to form a second solution; (e) a third step of

adding 250 ml of sterile water to the second solution to form a third solution; (d) a fourth step of

adding 6M hydrochloric acid to the third solution to form a fourth solution; and (e) a fifth step of

adding dilute hydrochloric acid and sterile water to the fourth solution to form a final solution

The dosage formulation of claim 1 in the form of tablets, capsules, dispersions, or suspensions.

Claims 11-27. (cancelled)

28. (currently amended) A method of treating hematological malignancies in a

subject in need thereof, the method comprising orally administering to the subject a

therapeutically effective amount of an arsenic trioxide composition with fewer side effects than

the same amount of arsenic trioxide administered intravenously, wherein the arsenic trioxide

composition is prepared by a method comprising: (a) a first step of adding 500 mg of arsenic

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trioxide to 150 ml of sterile water to form a first solution; (b) a second step of adding 3M sodium bydroxide to said first solution to form a second solution; (c) a third step of adding 250 ml of

sterile water to said second solution to form a third solution; (d) a fourth step of adding 6M

hydrochloric acid to said third solution to form a fourth solution; and (e) a fifth step of adding

dilute hydrochloric acid and sterile water to said fourth solution to form a final solution.

29. (currently amended) The method of claim 28, wherein the arsenic trioxide in step

(a) is a powder.

30. (original) The method of claim 29, wherein the arsenic trioxide powder has at

least 90%, 95%, 96%, 97%, 98% or 99% purity.

31. (currently amended) The method of claim 28, wherein the arsenic trioxide is

incompletely dissolved in the first or dispersed in a solution.

32. (currently amended) The method of claim 28, wherein the arsenic trioxide is

completely dissolved prior to adding the hydrochloric acid in step (d) administered in a dosage of

5 to 10 mg/day.

33. (currently amended) The method of claim 28, wherein the arsenic trioxide is in a

solution having a pH of the fourth solution has a pH of 8.0.

34. (currently amended) The method of claim 28, wherein the final arsenic trioxide is

in a solution has having a pH of 7.2.

Claims 35-37. (cancelled)

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38. (currently amended) The method of claim 37 28, wherein the arsenic trioxide composition is orally administered to the subject at intervals for periods of at least a month or longer.

- 39. (previously presented) The method of claim 28, wherein the therapeutically effective amount is 10 mg per day.
- 40. (original) The method of claim 28, wherein the hematological malignancies is selected from the group consisting of acute myeloid leukemia, acute nonlymphocytic leukemia, mveloblastic leukemia, promyelocytic leukemia, myelomonocytic leukemia, monocytic leukemia, erythroleukemia, myelodyspłastic syndrome, acute promyelocytic leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, hairy cell leukemia, polycythemia vera, Hodgkin's lymphoma, non-Hodgkin's lymphomas, myeloma, giant cell myeloma, indolent myeloma, localized myeloma, multiple myeloma, plasma cell myeloma, sclerosing myeloma, solitary myeloma, smoldering multiple myeloma, nonsecretary myeloma, osteosclerotic myeloma, plasma cell leukemia, solitary plasmacytoma, and extramedullary plasmacytoma.
- 41. (original) The method of claim 28, wherein the hematological malignancies is acute myeloid leukemia.
- (original) The method of claim 28, wherein the hematological malignancies is 42. acute promyelocytic leukemia.
- (new) The method of claim 28 further comprising administering one or more 43. additional chemotherapeutic agents.

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44. (new) The dosage formulation of claim 1 in combination with one or more additional chemotherapeutic agents.